IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

KATHLEEN WAGNER, Plaintiff, vs WYETH, and its divisions, WYETH PHARMACEUTICALS INC., and ESI LEDERLE, PHARMACIA and UPJOHN COMPANY, PHARMACIA CORPORATION, PFIZER INC, and GREENSTONE, LTD., and TEVA USA, and TEVA INDUSTRIES, BARR PHARMACEUTICALS, INC., BARR LABORATORIES Defendants.	:	Case No.: 3:13-cv-00497-BBC-SLC

BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Plaintiff Kathleen Wagner ("Plaintiff") brings this product liability action against Defendants Pfizer Inc. ("Pfizer"), Greenstone LLC ("Greenstone"), Pharmacia & Upjohn Company, LLC ("Upjohn"), Pharmacia, LLC and Wyeth LLC ("Wyeth") (collectively, "Defendants") alleging that Defendants' hormone therapy products – Provera and Cycrin (collectively, "HT") – were defective and caused her injury. Plaintiff alleges that she was prescribed Provera (manufactured by Upjohn), Cycrin (manufactured by Wyeth), and Medroxyprogesterone (manufactured by Barr Laboratories) by Dr. Jenny Hackforth-Jones "some time after February 1, 1995" until April 2010. (*See* Plaintiff's Answers to Interrogatories Nos. 2 and 20 from Defendant Wyeth's First Set of Interrogatories, Affidavit of Jason J. Franckowiak ("Aff of JJF"), Ex. A.) Plaintiff was diagnosed with breast cancer in April 2010 and alleges that her HT use caused her breast cancer and other injuries, including a staph infection, uterine and

colon polyps, and ovarian and kidney cysts. (*See* Plaintiff's Answers to Interrogatories Nos. 12 and 21 from Defendant Wyeth's First Set of Interrogatories, Aff of JJF, Ex. A.)

In her Amended Complaint, Plaintiff includes 12 purported causes of action titled Negligence (Count I), Strict Products Liability (Defective Product) (Count II), Strict Products Liability (Defective Design, Marketing and Inadequate Warnings) (Count III), Negligent Misrepresentation (Count IV), Breach of Express Warranty (Count V), Breach of Implied Warranty (Count VI), Intentional Misrepresentation and Fraud (Count VII), /Violations of State Consumer Fraud Act (Count VIII), Assault and Battery (Count IX), Intentional Infliction of Emotional Distress (Count X), Negligent Infliction of Emotional Distress (Count XI) and Gross Negligence/Malice (Count XII). (Plaintiff's Amended Complaint ("Am. Compl.") at ¶¶ 35-118.)

Each of Plaintiff's legal theories is without evidentiary or legal support, the most compelling of which is Plaintiff's lack of evidence to support her specific causation burden. As specific causation is a fundamental element for each of Plaintiff's claims, the lack of specific causation evidence is fatal to Plaintiff's entire case. In addition, Plaintiff lacks evidence to support her liability claims. Accordingly, Plaintiff's claims should be dismissed as a matter of law, as follows:

- All of Plaintiff's claims fail because she does not have the required evidentiary proof for establishing specific causation, which is necessary for each of her claims;
- Plaintiff's design defect claim fails because Plaintiff's only alleged claim is that the HT she ingested contained the wrong kind of progestin, and this claim is insufficient to succeed on a design defect claim under Wisconsin law;
- Plaintiff's claims for failure to warn, negligence, misrepresentation, breach of warranty, and consumer fraud are all premised on an alleged failure to warn and are thus barred by the learned intermediary doctrine;
- Plaintiff's reliance-based claims for misrepresentation and consumer fraud further fail because Plaintiff has no evidence that she or her prescribing physician relied on any statements from Defendants;

- Plaintiff's warranty claims fail for the independent reason that Wisconsin does not recognize a product liability cause of action for breach of warranty;
- Plaintiff's assault and battery claim fails because Plaintiff has no evidence of Defendants' intent;
- Plaintiff's gross negligence claim fails as a matter of law because Wisconsin law no longer recognizes a cause of action for gross negligence; and
- All of Plaintiff's claims against Pfizer and Greenstone fail as a matter of law because Plaintiff did not ingest a product manufactured or sold by either company.

For these reasons and as discussed in this brief, Defendants are entitled to summary judgment on all of Plaintiff's claims.

SUMMARY JUDGMENT STANDARD

Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex v. Catrett*, 477 U.S. 317, 322-23 (1986). Although the movant bears the initial burden of asserting the basis of its motion, the movant is not required to negate the opponent's claim. *Celotex*, 477 U.S at 323; *Terry v. Woods*, 803 F. Supp. 1519, 1522 (E.D. Wis. 1992). Rather, the movant must merely show "that there is an absence of evidence to support the non-moving party's case." *Celotex*, 477 U.S. at 325. When this burden is met, the nonmoving party is then required to "go beyond the pleadings and ... designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (Although the evidence is to be viewed in the light most favorable to the nonmoving party, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts"). An issue is not genuine if it is created by evidence that is "merely colorable" or is "not significantly probative." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986). Therefore, "to survive summary judgment, the nonmoving party must present

evidence sufficient to establish a triable issue of fact on all essential elements of its case." *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 702 (7th Cir.), *cert. denied*, 558 U.S. 1092 (2009).

ARGUMENT

I. PLAINTIFF'S CLAIMS FAIL BECAUSE SHE HAS NO REQUIRED PROOF OF SPECIFIC CAUSATION.

Plaintiff must establish a causal connection between the HT she ingested and her alleged injuries to succeed on any of her claims. *See, e.g., Tatera v. FMC Corp.*, 768 N.W.2d 198, 203 (Wis. Ct. App. 2009) (strict liability); *Hoida, Inc. v. M & I Midstate Bank*, 717 N.W.2d 17, 27 (Wis. 2006) (negligence); *Micro-Managers, Inc. v. Gregory*, 434 N.W.2d 97, 101 (Wis. Ct. App. 1988) (breach of warranty); *Kaloti Enters., Inc. v. Kellogg Sales Co.*, 699 N.W.2d 205 (Wis. 2005) (intentional misrepresentation); *Hatleberg v. Norwest Bank of Wis.*, 700 N.W.2d 15 (Wis. 2005) (negligent misrepresentation); *Rabideau v. City of Racine*, 627 N.W.2d 795, 803 (Wis. 2001) (intentional infliction of emotional distress); *Bowen v. Lumberments Mut. Cas. Co.*, 517 N.W.2d 432, 443 (Wis. 1994) (negligent infliction of emotional distress). It is not enough for Plaintiff to come forth with evidence that HT can generally cause the injuries at issue; it is Plaintiff's burden to prove that her HT use specifically caused *her* alleged injuries. *See Smith v. Sofamor, S.N.C.*, 21 F. Supp. 2d 918, 921 (W.D. Wis. 1998) ("To establish liability, a plaintiff must prove not only that the defendant's product was defective, but that the product was cause in fact of plaintiff's injury.") (applying Wisconsin law).

Moreover, given the complexity of the issues and subject matter of this case, expert testimony is needed to satisfy Plaintiff's causation burden. It is well-founded that to establish causation in a case where the issues involve technical, scientific or medical matters, beyond the common knowledge or experience of jurors, testimony from medical experts is essential. *Ollman v. Wis. Health Care Liab. Ins. Plan*, 505 N.W.2d 399 (Wis. Ct. App. 1993). "[T]he lack

of expert testimony on the question of causation results in an insufficiency of proof . . . ." *Bruss v. Milwaukee Sporting Goods Co.*, 150 N.W.2d 337, 341 (Wis. 1967); *see also Smith* 21 F. Supp. 2d at 921 (holding that a medical device case "requires medical testimony to establish causation between the device and plaintiff's injury"); *Valente v. Sofamor, S.N.C.*, 48 F. Supp. 2d 862, 867-68 (E.D. Wis. 1999) (recognizing that "the plaintiffs must present expert testimony establishing causation between their injuries and defects" in the medical devices at issue).

Plaintiff has entirely failed to meet her specific causation burden. She has not identified even one expert witness that will establish a causal connection between the HT she ingested and her alleged injuries. Plaintiff has only provided a report for one expert, epidemiologist Dr. Donald Austin. While Dr. Austin may give an opinion on general causation with respect to HT, his report does not contain any opinion on the specific cause of *this* Plaintiff's injuries. (*See* Report and Curriculum Vitae of Dr. Donald V. Austin, MD, MPH, Aff of JJF, Ex. B.)[1] The only other witnesses disclosed by Plaintiff to offer expert testimony are five of her treating physicians,[2] none of whom has provided an expert report. To the extent that Plaintiff now contends that one treater (Dr. Mack) may "possibly" testify as to causation of Plaintiff's cancer, Plaintiff testified that none of her treating physicians has ever told her that her alleged injuries are all related in any way to her use of HT. Further, none of her treating physicians noted in their medical records that they believed her HT use was in any way related to her diagnosis of breast

[1] Issues relating to Dr. Austin's report, which relates solely to issues of general causation, will be addressed in Defendants' motions *in limine*.

[2] Plaintiff also disclosed Dr. Judy Schmidt as an expert regarding "Plaintiff's medical facts." However, Plaintiff has never timely served an expert report from Dr. Schmidt, and thus her disclosure was improper under the Federal Rules of Civil Procedure. The Court has already concluded that Plaintiff cannot rely on a non-treating expert if no report has been served for that expert. *See* Dkt. 93 ("If plaintiff failed to submit required expert reports for any of her planned expert witnesses by March 9, 2015, she will not be allowed to use those witnesses as experts in this case.")

cancer. (*See* Dep. Tr. of Kathleen Wagner ("Plaintiff's Dep.") at 239:23-242:17, 312:5-313:18, Aff of JJF, Ex. D.)

Establishing specific causation is not only Plaintiff's burden but it is fundamental to the viability of Plaintiff's case. Because Plaintiff has no expert witness to establish specific causation, she therefore has not met her burden of proof on causation, and Defendants are entitled to summary judgment on all of her claims.

II. PLAINTIFF'S DESIGN DEFECT CLAIM FAILS AS A MATTER OF LAW.

Although Plaintiff's failure to establish specific causation applies to all of her claims, Plaintiff's design defect claim further fails under Wisconsin law. Specifically, Plaintiff cannot maintain a defective design claim on allegations related to the product's ingredients when that ingredient is a characteristic of the product itself. *Godoy v. EI. Du Pont De Nemours and Co*., 768 N.W.2d 674, 683-86 (Wis. 2009) (holding that white lead carbonate pigment is not "defectively designed" based on the presence of lead, a characteristic ingredient of the product). "[A] product cannot be defectively designed when that design is inherent in the nature of the product so that an alternative design would make the product something else." *Id.* at 680. In addition, the Court explained, "We … acknowledge that some ingredients cannot be eliminated from a design without eliminating the product itself. *When the ingredient cannot be designed out of the product, the Restatement (Second) instructs that although other claims may be asserted, the proper claim is not design defect*." *Id.* at 687 (emphasis added).

With respect to a potential design defect claim, viewed liberally, Plaintiff's allegations boil down to: (1) The active ingredient of Provera and Cycrin is medroxyprogesterone acetate; (2) medroxyprogesterone acetate is a synthetic progestin; (3) bioidentical progesterone, which has a different chemical structure than synthetic versions, is a safer alternative than

medroxyprogesterone acetate; and (4) Defendants' HT products are defectively designed because they contain medroxyprogesterone acetate rather than bioidentical progesterone. Under the Wisconsin Supreme Court's reasoning in *Godoy*, however, these allegations fail as a matter of law because by definition Provera and Cycrin contain medroxyprogesterone acetate and a design defect claim cannot be predicated upon an essential element of the product. As the *Godoy* Court stated:

> Lead is a characteristic ingredient of white lead carbonate pigment. By definition, white lead carbonate pigment contains lead. Removing lead from white lead carbonate pigment would transform it into a different product. Under these circumstances, we conclude that the design of white lead carbonate pigment is not defective.

Id. at 684. If "medroxyprogesterone acetate" is substituted for "lead" and "Provera and Cycrin" for "white lead carbonate pigment" in the above passage from *Gody*, it is readily apparent that the HT ingested by Plaintiff is not defectively designed under Wisconsin law merely because it contains medroxyprogesterone acetate. Simply stated, if medroxyprogesterone acetate had been removed from Provera and Cycrin, doing so would have transformed them into different products. That fact alone precludes Plaintiff's design defect claim under Wisconsin law.

By clear and straight-forward extension of the Wisconsin Supreme Court's holding in *Godoy*, any claim in this case based on design defect fails as a matter of law.

III. PLAINTIFF'S FAILURE-TO-WARN, NEGLIGENCE, MISREPRESENTATION, BREACH OF WARRANTY AND CONSUMER FRAUD CLAIMS FAIL AS A MATTER OF LAW.

A. Plaintiff Has No Admissible Testimony that Defendants' Warnings Were Inadequate.

As this Court has recognized, "[m]ost of Wagner's claims (negligence, strict products liability, misrepresentation, breach of warranty, and consumer fraud) can be characterized as

failure-to-warn claims, defective-design claims, or both." *Wagner v. Pfizer Inc., et al.*, 2014 WL 3447476, *3 (W.D. Wis. July 11, 2014). In addition to the lack of specific causation proof, which is fundamental to each of these claims, Plaintiff's "failure-to-warn" claims also fail because Plaintiff has no admissible expert testimony that Defendants' HT warnings were inadequate. In a failure-to-warn case, the plaintiff must establish that the warning was inadequate. *See Menges*, 61 F. Supp. 2d at 830. Here, Plaintiff has not disclosed any expert to provide testimony regarding the adequacy of the warnings placed on Provera or Cycrin.

Under Wisconsin law, expert testimony is necessary where the subject matter is outside the realm of ordinary experience and lay comprehension. *See, e.g., Weiss v. United Fire and Cas. Co.*, 541 N.W.2d 753, 757 (Wis. Ct. App. 1995) ("Thus, for example, we have required expert testimony in many cases involving medicine, precisely because medical practice demands "special knowledge or skill or experience on subjects which are not within the realm of the ordinary experience of mankind, and which require special learning, study, or experience.'") (quoting *Cramer v. Theda Clark Mem. Hosp.*, 172 N.W.2d 427 (Wis. 1969)). It is well-established that because the warnings accompanying a prescription medication are directed to physicians rather than patients, only physicians or others with similar expertise concerning pharmaceuticals are qualified to speak to the adequacy of the warning, as this subject is not within the realm of experience of any ordinary prudent person or juror. *See, e.g., Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990) ("the adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony"); *Demmler v. SmithKline Beecham Corp.*, 448 Pa.Super. 425, 671 A.2d 1151, 1154 (1996) ("Generally, expert medical testimony is required to determine whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be

complex medicines, esoteric in formula and varied in effect."); *Dion v. Graduate Hosp. of University of Pennsylvania*, 520 A.2d 876, 881 (Pa. 1987) (expert testimony is required to determine the adequacy of a drug manufacturer's warning when that warning is directed to the medical community, rather than the general public, and requires specialized skill or knowledge); *Carlsen v. Javurek*, 526 F.2d 202, 206 (8th Cir. 1975) (upholding directed verdict in favor of drug manufacturer where plaintiff offered no expert testimony that pharmaceutical drug warning was inadequate); *Hill v. Squibb & Sons, E. R.*, 592 P.2d 1383, 1388 (Mont. 1979) (in matters with respect to which a layman can have no knowledge at all, such as the adequacy of a warning directed at physicians, the court and jury must depend upon expert evidence); *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So.2d 688, 692 (Miss. 1988) (it is generally accepted that the adequacy of warnings accompanying prescription drugs is a subject so distinctively related to medical science as to be beyond the kin of the average lay person); *Northern Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1035-36 (Ill. App. Ct. 1991) (like medical malpractice actions, expert testimony is needed in negligence and/or product liability actions involving prescription drugs, premised on the drug manufacturer's alleged failure to warn).

However, here, Plaintiff's disclosures and expert report are devoid of any reference relating to the adequacy of Defendants' warnings. Plaintiff has listed five of her treating physicians as experts.[3] (*See* Plaintiff's Expert Disclosures, Aff of JJF, Ex. C.) Plaintiff's Expert Disclosures contain no reference to any expected testimony by these physicians regarding the Provera or Cycrin product labeling. In addition, Plaintiff has provided a report from epidemiologist Dr. Austin.[4] Dr. Austin does not offer the required testimony related to the adequacy of Defendants' warnings. Regarding Dr. Austin, Plaintiff's Expert Disclosures state

[3] *See supra*, fn. 3.

[4] *See supra*, fn. 2.

only: "his Vitae contains his specifics along with his report" (*see id.* at 6), and neither his report nor his curriculum vitae contain any reference to the Provera or Cycrin product labeling. (*See* Report and Curriculum Vitae of Dr. Donald V. Austin, MD, MPH, Aff of JJF, Ex. B.) Accordingly, because none of the experts designated by Plaintiff will provide testimony regarding the adequacy of the Provera or Cycrin product labeling, Defendants are entitled to summary judgment on Plaintiff's failure-to-warn claims.

B. Plaintiff has Failed to Establish Proximate Cause for Negligence, Misrepresentation, Breach of Warranty, and Consumer Fraud.

1. These Claims Are "Failure-to-Warn" Claims Subject to the Learned Intermediary Doctrine.

Plaintiff's claims for failure to warn, negligence, misrepresentation, breach of warranty, and consumer fraud are all premised on an alleged failure to warn and are thus subject to the learned intermediary doctrine. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 744 (S.D. W. Va. 2014) (noting that "courts around the country have extended the learned intermediary doctrine to all claims based on a manufacturer's failure to warn, including claims for fraud, misrepresentation, and breach of warranty") (collecting cases). The majority of Plaintiff's claims in this case – regardless of how they are characterized – boil down to an alleged failure to warn her prescribing physician of the risk of breast cancer. These claims are subject to the learned intermediary doctrine and the rules of proximate cause applicable to such prescription drug cases.

Under Wisconsin's product liability law, a "product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably

safe." WIS. STAT. ANN. § 895.047. Similarly, to succeed on the merits of a negligent failure to warn claim, Plaintiff must establish a failure to warn adequately and that the failure to warn proximately caused Plaintiff's injuries. *See Kessel ex rel. Swenson v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211 (Ct. App. Wis. 2006) (citations omitted).

Though the Wisconsin Supreme Court has not yet addressed the application of the learned intermediary doctrine, federal courts applying Wisconsin law have predicted that Wisconsin would apply the learned intermediary doctrine to prescription medical product cases. *See Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999); *Monson v. AcroMed Corp.*, 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 963 (E.D. Wis. 1981), *modified on other grounds*, 523 F. Supp. 206 (E.D. Wis. 1981). *But see Maynard v. Abbott Laboratories*, 2013 WL 695817, *5 (E.D. Wis. Feb. 26, 2013) (declining to apply learned intermediary doctrine). Further, a Wisconsin state trial court has followed the rule and recognized that "courts of numerous other jurisdictions almost universally hold that in the case of prescription drugs, a manufacturer's provision of proper warnings to a prescribing physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug except through the physician." *Straub v. Berg*, 2003 WL 26468454 (Wis. Cir. Jan. 6, 2003) (citing *Lukaszewicz*, 510 F. Supp. at 962). Provera and Cycrin are prescription medications only available through a physician. Thus, Defendants' duty to warn lied with Plaintiff's prescriber, the learned intermediary, not Plaintiff.

Courts have identified sound reasons for the learned intermediary doctrine. For example, if manufacturers "were required to warn of every suspected risk that could possibly attend the use of a medicine, the consuming public would be so barraged with warnings that it would undermine the effectiveness of those warnings." *Doe v. Miles, Inc.*, 2000 WL 667383, at *16

(Mo. App. Ct. May 23, 2000) (citation and internal quotation omitted); *accord*, *Brooks v. Medtronic,* 750 F.2d 1227, 1232 (4th Cir. 1984) (direct warnings to the consumer would be "almost inevitably involved and long winded" and frequently "not in the patient's best interest"). Instead, the physician, "through education, experience and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient." *Thomas v. Hoffman-LaRoche, Inc*., 731 F. Supp. 224, 229 (N.D. Miss. 1989), *aff'd*, 949 F.2d 806 (5th Cir.), *cert. denied*, 504 U.S. 956 (1992); Restatement (Third) of Torts: Products Liability, § 6, Comment b (1998) ("only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy"). Some patients who vitally need a particular medication might be unwilling to take it if they were informed of every conceivable risk, no matter how remote. For these reasons, "[t]he physician decides what facts should be told to the patient." *Terhune v. A.H. Robins* Co., 577 P.2d 975, 978 (Wash. 1978).

The application of the learned intermediary doctrine is particularly appropriate here, as Plaintiff testified that she relied on Dr. Hackforth-Jones' judgment in deciding to take HT. (*See* Plaintiff's Dep. at 203:1-8, Aff of JJF, Ex. D) At deposition, Plaintiff repeatedly testified that it was Dr. Hackforth-Jones' decision to prescribe HT and that the doctor had to convince Plaintiff to take the medicine. (*See, e.g., id.* at 212:10-12 ("I didn't have any complaints to start using it. I mean, the idea of starting to use it wasn't my idea to begin with."); *id.* at 40:16-23 ("But I guess just because I hadn't wanted to take the medication -- that medication to begin with, and my doctor just convinced me to take it. And that's probably why, because I was never -- really wanted to take it to start out with. But she was adamant about the fact that if I didn't take it, I

would get uterine cancer because the uterine lining would build up because of the weight issue."))

Summary judgment is warranted on Plaintiff's failure to warn claims because Plaintiff cannot prove that any alleged inadequacy in Defendants' warnings was the proximate cause of Plaintiff's injuries as any change to the warnings would not have affected Dr. Hackforth-Jones' decision to prescribe Provera or Cycrin for Plaintiff.

2. Plaintiff Cannot Establish Proximate Cause For Her Warning Claims.

To prove proximate cause, Plaintiff must prove that a different warning would have altered the behavior of those involved in the case and the inadequate warning was a substantial factor in causing the injuries. *See Burke v. Poeschl*, 156 N.W.2d 378, 382 (Wis. 1968); *Schroeder v. Chapman*, 90 N.W.2d 579, 584 (Wis. 1958). Plaintiff cannot prove proximate cause here for two distinct reasons. First, Dr. Hackforth-Jones testified that she never reviewed the warnings accompanying the HT she prescribed Plaintiff during the time of treatment and therefore Defendants' allegedly inadequate warning could not have proximately caused Plaintiff's injuries. Second, Dr. Hackforth-Jones testified that, in light of what she knows now, she would still prescribe HT for Plaintiff.

Dr. Hackforth-Jones testified that she did <u>not</u> review any of the HT labeling materials before prescribing those medications for Plaintiff. Specifically, Dr. Hackforth-Jones testified as follows:

> Q No? Have you -- to the best of your recollection, have you ever reviewed the PDR regarding Provera, Cycrin, or MPA?
>
> A Not to my recollection.

(Dep. Tr. of Jenny T. Hackforth-Jones, M.D. ("Hackforth-Jones Dep.") at 44:2-5, Aff of JJF, Ex. E.) The Physicians' Desk Reference ("PDR") is the printed information provided for

physicians by manufacturers that contains the prescribing information for a drug, including its indications, contraindications, warnings, risks, and precautions. Dr. Hackforth-Jones' testimony that she did not review this information establishes that a different warning could not possibly have changed Dr. Hackforth-Jones' decision to prescribe. Courts across the country have embraced this proposition. *See e.g.*, *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir. 2003) ("when a physician fails to read or rely on a drug manufacturer's warnings, such failure constitutes the intervening, independent and sole proximate cause of the plaintiff's injuries, even where the drug manufacturer's warnings were inadequate") (applying Wyoming law); *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) ("the doctor who prescribed [the drug] . . . failed to read [the defendant's] published warnings before prescribing the drug. Because the doctor testified that he did not read the warning label that accompanied [the drug] or rely on information provided by [the manufacturer's] detail men before prescribing the drug to [plaintiff], the adequacy of [the] warnings is irrelevant") (applying California law); *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 277 (5th Cir. 2010) (prescriber "did not recall ever reading the package insert for the drug or consulting the Physician's Desk Reference. Her lack of memory, of course, does not preclude the possibility that she had read these materials, but neither can it sustain [plaintiff's] burden."). Accordingly, Plaintiff cannot establish proximate cause with respect to her failure-to-warn claims.

Plaintiff's failure-to-warn claims also fail because Plaintiff cannot prove that Dr. Hackforth-Jones would have chosen a different course of treatment if provided with a different warning. In fact, Dr. Hackforth-Jones testified that she stands behind her decision to prescribe HT for Plaintiff and would do so again today:

> Q Okay. And -- but at any rate, if she did come to you today, you would still -- as she did when you first prescribed Provera to her in 1994, you would still prescribe it to her today?
>
> A Yeah.
>
> Q Do you stand behind your decision in 1994 to prescribe Provera to her?
>
> A Yes.

(Hackforth-Jones Dep. at 56:21-57:3, Aff of JJF, Ex. E.) Thus, any alleged defective or absent warning was not the proximate cause of Plaintiff's injuries. *See Menges*, 61 F. Supp. 2d at 830 ("[A] plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff.") (applying Wisconsin law).

The learned intermediary doctrine precludes Plaintiff's failure to warn claims. Even if Defendants' warnings were in some way inadequate, Plaintiff has offered no evidence that the inadequacy was the proximate cause of her injuries. Therefore, Defendants should be granted summary judgment on Plaintiff's failure to warn claims.

IV. PLAINTIFF HAS NO COGNIZABLE CLAIMS FOR BREACH OF WARRANTY.

In addition to failing under the learned intermediary doctrine and for lack of specific causation evidence, Plaintiff's breach of warranty claims are inappropriate under Wisconsin law because "it is inappropriate to bring an action for breach of warranty where a tort remedy is sought." *Austin v. Ford Motor Co.*, 273 N.W.2d 233, 240 (Wis. 1979). In *Austin*, the Wisconsin Supreme Court determined that tort claims and breach of warranty claims may not be brought in the same action: "plaintiffs [can] not encumber the case by trying it on the duplicative theories of strict product liability and implied breach of warranty." *Id.* at 241. Here, Plaintiff is seeking tort remedies on the basis of several causes of action (e.g., strict liability, negligence, emotional

distress, misrepresentation, and fraud). (*See* Am. Compl. at Counts I-IV, VII.) In addition, Plaintiff is also seeking recovery under breach of warranty causes of action. (*See id.* at Counts V-VI.) This is precisely what the Wisconsin Supreme Court, in *Austin*, said plaintiffs could not do. Wisconsin law makes clear that it is inappropriate for Plaintiff to assert both tort claims and breach of warranty claims in the same action. Consequently, Defendants are entitled to summary judgment in their favor with respect to Plaintiff's breach of warranty claims.

In addition, privity of contract is a requirement for a breach of warranty claim. *Northridge Co. v. W.R. Grace & Co*., 471 N.W.2d 179, 187 n.15 (Wis. 1991). The plaintiff was not in privity with Defendants and thus this claim fails as a matter of law. Consequently Defendants are entitled to summary judgment in its favor on Plaintiff's breach of warranty claims.

V. PLAINTIFF'S RELIANCE-BASED CLAIMS ALL FAIL.

While Plaintiff's claims for negligent misrepresentation (Count IV), intentional misrepresentation and fraud (Count VII) and violations of the state consumer fraud act (Count VIII) all fail under the learned intermediary doctrine and for lack of specific causation, those claims further fail because Plaintiff has not shown that she or Dr. Hackforth-Jones relied on Defendants' allegedly fraudulent representations when deciding to prescribe or ingest HT. Under Wisconsin law, reliance is a necessary element of claims for negligent misrepresentation, fraud, and for violations of the Wisconsin consumer protection laws. *See, e.g.*, *Malzewski v. Rapkin*, 723 N.W.2d 156, 162-65 (Wis. Ct. App. 2006) (noting that reliance is an element of intentional misrepresentation, negligent misrepresentations, and consumer fraud claims made pursuant to WIS. STAT. ANN. § 100.18); *Novell v. Migliaccio*, 749 N.W.2d 544, 552-54 (Wis. 2008) (same). In *Valente v. Sofamor*, 48 F. Supp. 2d 862 (E.D. Wis. 1999), the Eastern District

dismissed claims for fraud and violations of WIS. STAT. ANN. § 100.18 against the manufacturer of a bone screw device because plaintiffs failed to show that they or their doctors relied on the defendants' allegedly fraudulent representations when they elected to undergo spinal fusion surgery. *Id.* at 873-874.

As was the case in *Valente*, Plaintiff here cannot demonstrate the necessary reliance to support her claims. Plaintiff herself admits that she does not recall doing any research or seeing any material related to progestins generally or Provera specifically before she took the medication. (*See* Plaintiff's Dep. at 192:17-22, 199:17-25, Aff of JJF, Ex. D.) In fact, Plaintiff had never even heard of Provera before Dr. Hackforth-Jones prescribed it for her. (*Id.* at 201:19-25 ("As I said earlier, if it had not been for Dr. Hackforth-Jones prescribing it and, you know, telling me what's going to happen if I don't, I would have never even heard of it.")) Nor can Plaintiff point to any evidence in the record that Dr. Hackforth-Jones relied on any statements from Defendants in making the medical decision to prescribe synthetic progestin for Plaintiff. Dr. Hackforth-Jones did not review the PDR entry for Provera or progestin before prescribing it to Plaintiff. (Hackforth-Jones Dep. at 43:15-44:1, Aff of JJF, Ex. E.) In fact, Dr. Hackforth-Jones has no recollection of ever reviewing the PDR regarding Provera, Cycrin or MPA. (*Id.* at 44:2-5.)

Because Plaintiff has no evidence of reliance, her claims for negligent misrepresentation, intentional misrepresentation and fraud and violations of the state consumer fraud act all fail

VI. PLAINTIFF HAS NOT EXPERIENCED EMOTIONAL DISTRESS AND THEREFORE HER CLAIMS FOR EMOTIONAL DISTRESS FAIL.

Plaintiff's claims for intentional infliction of emotional distress (Count X) and negligent infliction of emotional distress (Count XI) should be dismissed because Plaintiff has repeatedly failed to identify any emotional distress allegedly related to her use of Provera. To succeed on a

claim for intentional infliction of emotional distress, Plaintiff must establish that she "suffered an extreme disabling emotional response to the defendant's conduct." *Rabideau v. City of Racine*, 627 N.W.2d 795, 803 (Wis. 2001). Similarly, to succeed a negligent infliction of emotional distress claim, Plaintiff must establish that she suffered "severe emotional distress." *Bowen v. Lumberments Mut. Cas. Co.*, 517 N.W.2d 432, 443 (Wis. 1994).

Plaintiff has failed to establish that she has experienced "an extreme disabling emotional response to the defendant's conduct" or "severe emotional distress." For example, Plaintiff stated in her discovery responses that she is not claiming psychological, psychiatric (including depression), cognitive or emotional injury from her use of hormone therapy. (*See* Plaintiff's Response to Interrogatory 17 from Wyeth's First Set of Interrogatories, Aff of JJF, Ex. A.) Plaintiff, who signed her interrogatory responses herself, has thus admitted under oath that she does not have an emotional injury related to her use of Provera. Additionally, when asked at her deposition about an emotional injury, Plaintiff repeatedly failed to identify any emotional injury that she has suffered. (*See* Plaintiff's Dep. at 242:18-245:21, Aff of JJF, Ex. D.)

Because Plaintiff has failed to establish an essential element of her emotional distress claims, Defendants are entitled to judgment as a matter of law on those claims.

VII. PLAINTIFF'S ASSAULT AND BATTERY CLAIMS FAIL FOR LACK OF EVIDENCE.

Under Wisconsin law, "a battery or assault and battery is a common law tort that has been defined as an intentional contact with another, which is unpermitted." *Estate of Thurman v. City of Milwaukee*, 197 F. Supp. 2d 1141, 1151 (E.D. Wis. 2002) (citing *McCluskey v. Steinhorst*, 173 N.W.2d 148 (Wis. 1970)). Claims for assault and battery must be dismissed absent an intent to do harm. *See Brabazon v. Joannes Bros. Co.*, 286 N.W. 21, 26 (Wis. 1939). Here, Plaintiff has failed to come forth with any evidence to support a contention that Defendants

intended to cause her harm. Because of that failure of proof, Defendants are entitled to summary judgment on Plaintiff's assault and battery claims.

VIII. WISCONSIN NO LONGER RECOGNIZES A CAUSE OF ACTION FOR GROSS NEGLIGENCE.

Plaintiff's claims for gross negligence/malice (Count XII) should be dismissed because Wisconsin no longer recognizes a cause of action for gross negligence. *See, e.g., Bielski v. Schulze*, 114 N.W.2d 105, 111-12 (Wis. 1962) ("The history of the development of gross negligence, its reason for existing, the content of the concept, and the inequitable results and consequences of its application have led us to decide the doctrine of gross negligence, as we know it, should be interred in the limbo of jurisprudence along side the doctrine of assumption of risk in negligence cases."), *overruled in part on other grounds by Wangen v. Ford Motor Co.*, 294 N.W.2d 437 (1980); *Heritage Farms, Inc. v. Markel Ins. Co.*, 762 N.W.2d 652, 664 (recognizing that *Bielski* abolished the concept of gross negligence under Wisconsin law).

IX. ALL OF PLAINTIFF'S CLAIMS AGAINST GREENSTONE AND PFIZER FAIL BECAUSE PLAINTIFF CANNOT PROVE SHE INGESTED A PRODUCT MANUFACTURED OR SOLD BY THEM.

Moreover, under Wisconsin law, a defendant cannot be held liable in a product liability case if it does not manufacture, sell or distribute any of the products that allegedly caused the plaintiff's injuries. *See* WIS. STAT. ANN. § 895.047 (limiting liability to manufacturers, sellers and distributors of products). Here, there is no evidence in the record that Plaintiff ingested any hormone therapy medications manufactured or sold by Pfizer or Greenstone. Thus, summary judgment should be entered on all counts as they relate to Greenstone and Pfizer.

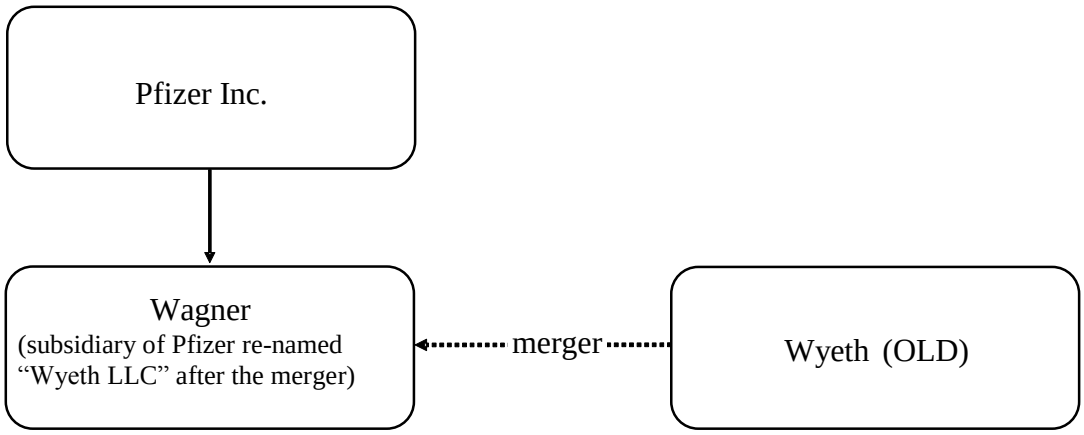
Plaintiff alleges that for more than 10 years she ingested "Provera by Upjohn and Company; Cycrin by Wyeth, Medroxyprogesterone by Barr Laboratories" and that she was injured as a result. (*See* Plaintiff's Response to Interrogatory 20 from Wyeth's First Set of

Interrogatories, Aff of JJF, Ex. A.) To recover against Pfizer or Greenstone under Wisconsin law, Plaintiff must establish that a product manufactured or sold by Pfizer or Greenstone caused her harm. There is no other evidence in the record indicating that Plaintiff ingested a hormone therapy drug manufactured or distributed by Pfizer or Greenstone. Accordingly, summary judgment should be entered in favor of Pfizer and Greenstone.

X. THERE IS NO BASIS IN LAW OR FACT TO IMPOSE LIABILITY ON PFIZER BASED ON PLAINTIFF'S ALLEGED USE OF WYETH'S CYCRIN AND UPJOHN'S PROVERA.

Recognizing that she never ingested a Pfizer product, Plaintiff nevertheless attempts to hold Pfizer liable by alleging that it is the "successor in interest" to Wyeth and Upjohn *See* Plaintiff's Amended Complaint at § I, ¶¶ b)(i and ii). However, there is simply no basis in fact or law to impose liability on Pfizer.

On January 25, 2009, Pfizer, Wyeth and Wagner Acquisition Corporation ("Wagner") entered into a merger agreement ("the Pfizer-Warner-Wyeth Merger Agreement") under which Wyeth merged with Wagner, a subsidiary of Pfizer.[5] A graphic depicting the structure of the merger is set forth below:



[5] *See* Pfizer-Warner-Wyeth Merger Agreement at § 1.1 (attached to the Aff of JJF, as Ex. F).

As such, Pfizer did not "merge" with Wyeth (or with any entity).

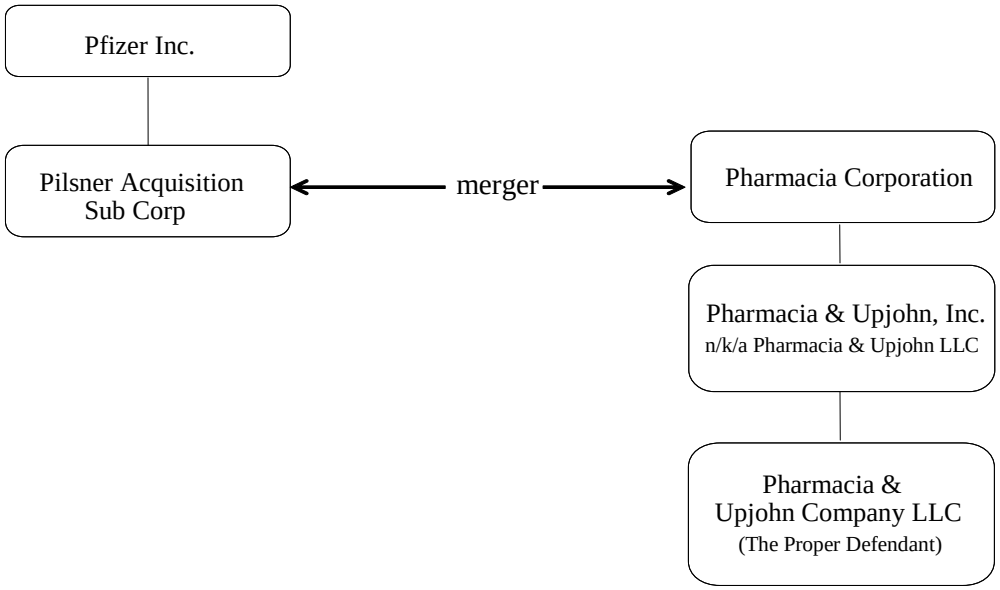
Following the acquisition and post-closing internal restructuring, the newly-formed entity is now known as "Wyeth LLC" and is a wholly-owned subsidiary of Pfizer.[6] Pursuant to Section 1.4 of the Pfizer-Warner-Wyeth Merger Agreement, "all debts, liabilities and duties" of Wyeth before the merger remained "the debts, liabilities and duties of the Surviving Corporation"—the Wagner-Wyeth entity renamed Wyeth LLC—after the merger.[7] In the words of the Court in the HT litigation in the United States District Court for the Eastern District of Arkansas, In Re: PREMPRO PRODUCTS LIABILTY LITIGATION (MDL DOCKET NO. 4:03-CV-1507-BRW) ("the MDL"), Pfizer's acquisition of Wyeth has "no effect on Plaintiff's claims against either [Pfizer or Wyeth]" because "Pfizer {would] not be 'acquiring the assets or liabilities of Wyeth.'"[8]

In 2003, Pfizer, through a wholly owned subsidiary, Pilsner Acquisition Sub Corp., indirectly acquired the stock of Pharmacia Corporation, the parent of Pharmacia & Upjohn, Inc. (now Pharmacia & Upjohn LLC), which is in turn the parent of Pharmacia & Upjohn Company LLC. Following is the current structure of the relevant entities:

[6] *Id.*

[7] *Id.* at § 1.4.

[8] *In re Prempro Prods. Liab. Litig.* (*Thompson v. Wyeth, Inc.*), Order, (E.D. Ark. Apr. 7, 2009), at 2 (denying reconsideration of order dismissing Pfizer because, among other reasons, "Plaintiffs do not allege that they took a Pfizer drug") (attached to the Aff of JJF, as Ex. G).



Thus, Upjohn is an indirect, wholly-owned subsidiary of Pfizer. Pfizer's 2003 acquisition of the stock of Pharmacia Corporation was not a merger between Pfizer and Upjohn or any other corporation and Pfizer assumed no liabilities in the transaction.[9]

It is hornbook law that a parent corporation is a separate and distinct legal entity from its subsidiary and that "a parent corporation, so-called because of control through ownership of another corporation's stock, is not liable for the acts of its subsidiaries." 18 Am. Jur. 2d Corporations § 61 (2008). *See Guining Li v. Citigroup, Inc.*, No. 99-C-635-C, 2000 WL 34237511, *2 (W.D. Wis. July 26, 2000) ("It is a general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation … is not liable for the acts of its subsidiaries.") (quoting *United States v. Bestfoods*, 524 U.S. 51, 61 (1998)).

The MDL Court has held that there is no factual or legal basis for a claim against Pfizer. Pfizer's acquisition of Wyeth has "no effect on Plaintiff's claims against either [Pfizer or Wyeth]" because "Pfizer will not be 'acquiring the assets or the liabilities of Wyeth.'" *In re*

[9] *See* Pfizer-Pharmacia Merger Agreement at § 1.4 (excerpts attached to the Aff of JJF as Ex. H.)

Prempro Prods. Liab. Litig. (Bland v. Wyeth), No. 4:04-cv-1272 Order, at 1-2 (E.D. Ark. Apr. 7, 2009) (denying reconsideration of order dismissing Pfizer because, among other reasons, "Plaintiff does not allege that she took a Pfizer drug"). *Accord*, *In re Prempro Prods. Liab. Litig. (Thompson v. Wyeth)*, No. 4:05-cv-0651 (E.D. Ark. Apr. 7, 2009) (same) (attached to the Aff of JJF as composite Ex. G). "Reversing or otherwise undermining the decisions by the MDL Court could lead to the type of inconsistent pretrial rulings that Congress sought to avoid, and therefore frustrate the very purpose of consolidation." *See Deutsch v. Novartis Pharm. Corp.*, Civil Action No. 09-cv-4677, 2011 WL 790702, *7 (E.D.N.Y. Mar. 8, 2011) (citing Manual for Complex Litigation § 20.133). The MDL Court correctly decided this issue and there is no basis to conclude otherwise in this case. Therefore, summary judgment should be entered.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant summary judgment in its favor on all of Plaintiff's claims.

Dated: March 16, 2015

Respectfully submitted,

/s/ Jason J. Franckowiak _____
Michael L. Johnson, Esq.; SBN 1056247
E-mail: mjohnson@otjen.com
Todd M. Weir, Esq.; SBN 1010442
E-mail: tweir@otjen.com
Jason J. Franckowiak, Esq.; SBN 1030873
Email: jfranckowiak@otjen.com
Otjen, Gendelman, Zitzer, Johnson & Weir, S.C.
20935 Swenson Drive, Suite 310
Waukesha, WI 53186
Phone: 262-777-2200

Counsel for Defendants Wyeth LLC, Pfizer Inc., Pharmacia & Upjohn Company LLC, Pharmacia LLC and Greenstone LLC

CERTIFICATE OF SERVICE

I hereby certify that I have on this 16th day of March, 2015 served the foregoing **Brief in Support of Defendants' Motion for Summary Judgment** by electronic filing with the Court's CM/ECF system.

/s/ Jason J. Franckowiak_
Counsel for Defendants